

The Examiner's various concerns under Section 112, second paragraph, have been addressed by the above editorial amendment to the claims, though the rejection regarding the use of "the cover material" does not appear to apply to claim 14, and has been addressed only by editorial amendment of claim 10.

With regard to the phrase "a stent cover portion", the specification and claims (e.g., claim 2) make clear that a graft can include an expandable portion and a stent cover portion. The cover portion, in turn, can be prepared from a porous material such as PET or ePTFE, and coated in the manner described.

With regard to claims 7 and 17, the phrase "active portions and domains thereof" applies to each member of the group.

The Examiner's concerns relating to claims 2 and 12 are confusing however, since the preamble of each seems quite proper for its intended purpose. Cited section 37 CFR 1.75(e) relates to *independent* claims, and in particular, to the use of "Jepson" style language, neither of which are relevant to claims 2 and 12.

Applicants appreciate but respectfully traverse the Examiner's suggestions regarding the reference incorporated by reference. The MPEP (Section 608.01(p)) clearly provides that it is proper to incorporate by reference such non-patent publications, without necessarily amending the application to include the material itself, particularly where the information provided is not "essential material" of the type contemplated therein.

The rejection under §102(e) based on Turnlund et al. (6,296,603 B1) is respectfully traversed. If anything, Turnlund et al. can be seen as teaching away from the method and graft of the present invention. The patent is concerned almost entirely with the use of irradiation, provided by a radioactive source, to increase the rate of thrombus formation and/or proliferative cell growth of a selected region of cellular tissue.

In turn, the use of a "biomaterial coating" such as collagen is described as merely an optional addition to the irradiation, and as such is relegated to mere passing mention in the specification. Nor, therefore, does Turnlund et al. describe the use of a bioactive agent coating that is *itself* sufficient to promote initial thrombus formation in the manner presently claimed, let alone one attached via photoreactive groups or providing the many features set forth in dependent claims.

The rejection under §103 over Turnlund et al. in view of Clapper (5,744,515) is respectfully traversed. Turnlund et al. is distinguished for the reasons provided above, and for others as well. Certainly Clapper et al. does nothing to remedy these defects of Turnlund et al. Moreover, the Action itself confirms that Turnlund et al. "fails to disclose" the attachment of collagen via photoreactive groups. At their closest, therefore, the combination of these references might suggest the use of photoreactive groups to attach the optional biomaterials used in the irradiation method set forth in Turnlund et al.

Applicants respectfully request that Examiner initial the remainder of references cited on our Supplemental Information Disclosure Statement filed August 14, 2001. The two references that were not initialed are:

1. U.S. Patent No. 4,326,532; Hammar; Issued 4/1982
2. U.S. Patent No. 4,822,361; Okita et. al.; Issued 4/1989

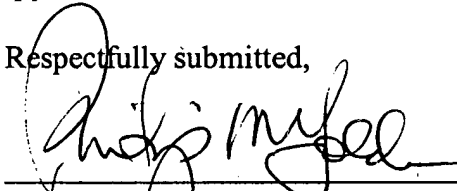
Finally, copies of pages 31 and 32, including both claim 21 and the Abstract are provided in response to Examiner's request.

Accordingly, entry of the present Amendment and reconsideration of the pending rejection is respectfully requested. The Examiner is encouraged to telephone the undersigned in the event any remaining issues arise.

The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,



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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amendments to the claims (where insertions are underlined and deletions placed in brackets):

4. (once amended) A graft according to claim 2 wherein the bioactive agent is covalently attached in the form of a thin, conformal coating on at least [the] an outer surface of the stent cover portion.

9. (once amended) A graft according to claim 2 wherein the agent is attached to the cover portion in a manner that provides a) a minimal increase in overall bulk, sufficient to permit the graft to be deployed in a minimally invasive fashion, and b) a combination of coating density, coating tenacity and bioactivity sufficient to permit the coating to substantially prevent endoleaking when deployed and used *in vivo*.

10. (once amended) An endovascular graft comprising an expandable stent portion and a porous stent cover portion selected from PET and ePTFE, the cover portion being coated with a bioactive agent comprising collagen, wherein the collagen is covalently attached in a thin, conformal coating to the [material] cover portion in a manner sufficient to promote initial thrombus formation followed by long term fibrous tissue ingrowth, and wherein the coating is covalently attached by the activation of photoreactive groups provided by the cover [material] portion, by the bioactive agent, and/or by a linking agent.

14. (once amended) A method according to claim 12 wherein the bioactive agent is covalently attached in the form of a thin, conformal coating on at least [the] an outer surface of the stent cover portion.

19. (once amended) A method according to claim 12 wherein the agent is attached to the cover portion in a manner that provides a) a minimal increase in overall bulk, sufficient to permit the graft to be deployed in a minimally invasive fashion, and b) a

combination of coating density, coating tenacity and bioactivity sufficient to permit the coating to substantially prevent endoleaking when deployed and used *in vivo*.

21. A method of preventing endoleaking in the course of deploying and using an endovascular graft that comprises an expandable stent portion and a stent cover, the method comprising the step of first coating the stent cover in the manner of claim 12.

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## ABSTRACT

An endovascular graft, e.g., having both an expandable stent portion and a stent cover portion positioned within and/or surrounding the expandable portion, the graft itself and/or a

5 stent cover portion being coated with a bioactive agent adapted to promote initial thrombus formation, preferably followed by long term fibrous tissue ingrowth. The endovascular graft addresses concerns regarding endoleaking by permitting the graft to be deployed and used in a manner that promotes a short term hemostatic effect in the perigraft region. This short term effect can, in turn, be used to promote or permit long term fibrous tissue ingrowth. Particularly

10 where the stent cover portion is prepared from a porous material selected from PET and ePTFE, the bioactive agent can include a thrombogenic agent such as collagen covalently attached in the form of a thin, conformal coating on at least the outer surface of the stent cover. An optimal coating of this type is formed by the activation of photoreactive groups provided by either the cover material itself, by the bioactive agent itself, and/or by a linking agent.